IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH,	)	
Plaintiff,	)	
	)	Civil Action No.: 06-222 JJF
v.	)	
	)	**JURY TRIAL DEMANDED**
IMPAX LABORATORIES, INC.,	)	
Defendant.	)	

ANSWER AND COUNTERCLAIMS OF DEFENDANT IMPAX LABORATORIES, INC., AND DEMAND FOR JURY TRIAL

Defendant and Counterclaim Plaintiff Impax Laboratories, Inc. ("Impax") hereby answers the numbered paragraphs of the Complaint for Patent Infringement of Plaintiff Wyeth ("Wyeth") as follows:

THE PARTIES

1. On information and belief, Impax admits that Wyeth is a Delaware corporation having its principal place of business at Five Giralda Farms, Madison, New Jersey 07940.

2. Impax admits that it is a Delaware corporation having its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544, and that it has a place of business at 3735 Castor Avenue, Philadelphia, Pennsylvania 19124. The remaining allegations of Paragraph 2 of the Complaint are denied.

NATURE OF THE ACTION

3. Impax admits that the Complaint purports to state a cause of action under the United States patent laws relating to an Abbreviated New Drug Application ("ANDA"), filed by

Impax with the U.S. Food and Drug Administration ("FDA") for approval to market a generic version of Wyeth's EFFEXOR® XR drug product sold in the United States. Impax denies the remaining allegations of Paragraph 3 of the Complaint.

JURISDICTION AND VENUE

4. Impax admits the allegations contained in Paragraph 4 of the Complaint.

5. Impax admits that it is incorporated in Delaware and has appointed a registered agent in Delaware. The remaining allegations of Paragraph 5 of the Complaint are denied.

6. For the purpose of answering this Complaint, Impax admits the allegations contained in Paragraph 6 of the Complaint.

7. For the purpose of answering this Complaint, Impax admits that venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(c) and 28 U.S.C. § 1400(b).

BACKGROUND

8. On information and belief, Impax admits that Wyeth is the holder of New Drug Application ("NDA") No. 20-699 for EFFEXOR® XR Capsules, a purported extended release dosage form containing Venlafaxine Hydrochloride. Impax lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 8 of the Complaint and on that basis denies each and every such allegation.

9. Impax admits that it filed an ANDA with the FDA, and that the FDA has assigned to the ANDA No. 78-057 under 21 U.S.C. § 355(j). Impax also admits that this ANDA was filed in order to obtain approval for the commercial manufacture, use, and sale of Venlafaxine HCl Extended-Release Capsules, in 37.5, 75 and 150 mg dosage strengths. Impax admits that it is seeking approval for generic versions of Wyeth's EFFEXOR® XR Capsules in 37.5, 75 and 150 mg dosage strengths. Impax denies the remaining allegations in Paragraph 9 of the Complaint.

10. Impax admits that in a letter dated February 21, 2006, Impax notified Wyeth that it had filed an ANDA seeking approval to market Venlafaxine HCl Extended-Release Capsules, in 37.5, 75 and 150 mg dosage strengths, and that it was providing information to Wyeth pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95. Impax admits that Wyeth received this letter on February 22, 2006. Impax lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 10 of the Complaint and on that basis denies each and every such allegation.

FIRST COUNT FOR INFRINGEMENT OF UNITED STATES PATENT NO. 6,274,171 B1

11. Impax admits that U.S. Patent No. 6,274,171 B1 ("the '171 Patent"), entitled "Extended Release Formulation of Venlafaxine Hydrochloride," was issued on August 14, 2001, and recites American Home Products Corporation as the assignee, but denies that it was duly and legally issued. Impax admits that Exhibit A to the Complaint appears to be a true and correct copy of the '171 Patent. Impax lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 11 of the Complaint and on that basis, denies each and every such allegation.

12. Impax admits that it filed ANDA No. 78-057 in order to obtain approval to market its Venlafaxine HCl Extended-Release Capsules in the United States before the expiration of the '171 Patent, but denies that its venlafaxine products infringe any valid and enforceable claim of the '171 Patent. Impax also admits that this ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), asserting that the claims of the '171 Patent were not infringed, and are invalid and/or unenforceable. The remaining allegations of Paragraph 12 of the Complaint are denied.

13. Impax denies each and every allegation in Paragraph 13 of the Complaint.

14. Impax denies each and every allegation in Paragraph 14 of the Complaint.

15. Impax denies each and every allegation in Paragraph 15 of the Complaint.

16. Impax denies each and every allegation in Paragraph 16 of the Complaint.

17. Impax denies each and every allegation in Paragraph 17 of the Complaint.

18. Impax denies each and every allegation in Paragraph 18 of the Complaint.

19. Impax denies each and every allegation in Paragraph 19 of the Complaint.

20. Impax denies each and every allegation in Paragraph 20 of the Complaint.

21. Impax denies each and every allegation in Paragraph 21 of the Complaint.

SECOND COUNT FOR INFRINGEMENT
OF UNITED STATES PATENT NO. 6,403,120 B1

22. Impax admits that U.S. Patent No. 6,403,120 B1 ("the '120 Patent"), entitled "Extended Release Formulation of Venlafaxine Hydrochloride," was issued on June 11, 2002, and recites Wyeth as the assignee, but denies that it was duly and legally issued. Impax admits that Exhibit B to the Complaint appears to be a true and correct copy of the '120 Patent. Impax lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 22 of the Complaint and on that basis, denies each and every such allegation.

23. Impax admits that it filed ANDA No. 78-057 in order to obtain approval to market its Venlafaxine HCl Extended-Release Capsules in the United States before the expiration of the '120 Patent, but denies that its venlafaxine products infringe any valid and enforceable claim of the '120 Patent. Impax also admits that this ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), asserting that the claims of the '120 Patent were not infringed, and are invalid and/or unenforceable. The remaining allegations of Paragraph 23 of the Complaint are denied.

24. Impax denies each and every allegation in Paragraph 24 of the Complaint.

25. Impax denies each and every allegation in Paragraph 25 of the Complaint.

26. Impax denies each and every allegation in Paragraph 26 of the Complaint.

27. Impax denies each and every allegation in Paragraph 27 of the Complaint.

28. Impax denies each and every allegation in Paragraph 28 of the Complaint.

29. Impax denies each and every allegation in Paragraph 29 of the Complaint.

30. Impax denies each and every allegation in Paragraph 30 of the Complaint.

31. Impax denies each and every allegation in Paragraph 31 of the Complaint.

32. Impax denies each and every allegation in Paragraph 32 of the Complaint.

THIRD COUNT FOR INFRINGEMENT
OF UNITED STATES PATENT NO. 6,419,958 B2

33. Impax admits that U.S. Patent No. 6,419,958 B2 ("the '958 Patent"), entitled "Extended Release Formulation of Venlafaxine Hydrochloride," was issued on July 16, 2002, and recites Wyeth as the assignee, but denies that it was duly and legally issued. Impax admits that Exhibit C to the Complaint appears to be a true and correct copy of the '958 Patent. Impax lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 33 of the Complaint and on that basis, denies each and every such allegation.

34. Impax admits that it filed ANDA No. 78-057 in order to obtain approval to market its Venlafaxine HCl Extended-Release Capsules in the United States before the expiration of the '958 Patent, but denies that its venlafaxine products infringe any valid and enforceable claim of the '958 Patent. Impax also admits that this ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), asserting

that the claims of the '958 Patent were not infringed, and are invalid and/or unenforceable. The remaining allegations of Paragraph 34 of the Complaint are denied.

35. Impax denies each and every allegation in Paragraph 35 of the Complaint.

36. Impax denies each and every allegation in Paragraph 36 of the Complaint.

37. Impax denies each and every allegation in Paragraph 37 of the Complaint.

38. Impax denies each and every allegation in Paragraph 38 of the Complaint.

39. Impax denies each and every allegation in Paragraph 39 of the Complaint.

40. Impax denies each and every allegation in Paragraph 40 of the Complaint.

41. Impax denies each and every allegation in Paragraph 41 of the Complaint.

42. Impax denies each and every allegation in Paragraph 42 of the Complaint.

43. Impax denies each and every allegation in Paragraph 43 of the Complaint.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

44. Impax is not infringing, has not infringed, nor will it infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '171, '120, or '958 Patents ("the Patents-in-Suit").

SECOND AFFIRMATIVE DEFENSE

45. An additional basis of non-infringement is made on the basis that statements, representations, admissions, and amendments made to the Patent Office during the prosecution of the applications which matured into the Patents-in-Suit, as well as the prior art, estops Plaintiff from asserting that the claims of said patents are infringed by any product of Impax.

THIRD AFFIRMATIVE DEFENSE

46. The claims of the '171, '120, and '958 Patents are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States

Code; including, but not limited to, anticipation, obviousness, lack of enablement, lack of written description, and indefiniteness in accordance with 35 U.S.C. §§ 102, 103, and/or 112.

FOURTH AFFIRMATIVE DEFENSE

47. The Patents-in-Suit are unenforceable because Wyeth has unclean hands.

COUNTERCLAIMS FOR AFFIRMATIVE RELIEF

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Impax hereby asserts counterclaims against Wyeth as follows:

48. Impax realleges and incorporates by reference its responses and allegations set forth in Paragraphs 1 through 47 hereof.

PARTIES

49. Counterclaim Plaintiff Impax, Inc. ("Impax") is a corporation in good standing incorporated under the laws of the State of Delaware, with its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544. It also has a place of business at 3735 Castor Avenue, Philadelphia, Pennsylvania 19124.

50. On information and belief, Counterclaim Defendant Wyeth, Inc. ("Wyeth") is a corporation incorporated under the laws of the State of Delaware, with its principal place of business in Madison, New Jersey.

JURISDICTION AND VENUE

51. Jurisdiction over this counterclaim is proper pursuant to 28 U.S.C. §§ 1331, 1338, and 2201-2202.

52. Because Wyeth sued Impax for patent infringement in this Judicial District, this Court has personal jurisdiction over Wyeth and venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c).

BACKGROUND

53. Impax is in the business of bringing lower cost generic drugs to the consumer.

54. Wyeth is an international conglomerate with over $18 billion dollars in revenue and over $3 billion dollars in net income in 2005. On information and belief, after obtaining FDA approval, Wyeth began selling an immediate release dosage form of venlafaxine hydrochloride in 1993. Wyeth still sells immediate release venlafaxine hydrochloride under the name EFFEXOR® for the treatment of depression.

55. On information and belief, Wyeth owns U.S. Patent No. 4,535,186, which claims the drug compound venlafaxine hydrochloride. This patent's expiration date was originally December 13, 2002, but it was extended under 35 U.S.C. § 156 for five years.

56. On information and belief, in an attempt to keep generic venlafaxine competition off the market beyond the expiration of U.S. Patent No. 4,535,186, Wyeth or its predecessor filed for provisional patent protection on March 25, 1996. Through multiple continuing applications, the Patents-in-Suit eventually issued.

57. On information and belief, Wyeth or its predecessor obtained FDA approval for an extended release venlafaxine hydrochloride dosage form and, through an aggressive marketing campaign, began converting the market from the immediate release product to this extended release form, called EFFEXOR® XR.

58. On information and belief, Teva Pharmaceuticals USA, Inc. ("Teva") filed an ANDA with the FDA to obtain approval to manufacture, use and sell an extended release venlafaxine hydrochloride dosage form, and provided certification to Wyeth that the '171, '120 and '958 Patents would not be infringed. Wyeth sued Teva for patent infringement in United States District Court, District of New Jersey. After extensive discovery, a Markman hearing was

held and that Court issued an order interpreting the claims of the '171, '120, and '958 Patents to be limited to a formulation comprising venlafaxine hydrochloride and microcrystalline cellulose. Copies of the Markman Order and Opinion are attached as Exhibit A. Thereafter, Wyeth settled the litigation with Teva but has maintained the terms of the settlement as a secret. As part of the settlement, the Markman Order was vacated.

59. Impax's venlafaxine extended release formulation does not contain microcrystalline cellulose and does not infringe the claims of the Patents-in-Suit.

FIRST COUNTERCLAIM
(Declaratory Judgment of Non-Infringement and Invalidity of U.S. Patent Nos. 6,274,171, 6,403,120, and 6,419,958)

60. An actual controversy exists between Wyeth and Impax concerning the '171, '120, and '958 Patents ("the Patents-in-Suit"), which requires a declaration of rights by this Court. This controversy relates to the alleged infringement, validity, and enforceability of the Patents-in-Suit.

61. Wyeth has asserted ownership of the Patents-in-Suit and that Impax's venlafaxine product will infringe the Patents-in-Suit.

62. Impax has not infringed, is not infringing, and will not infringe any of the claims of the Patents-in-Suit, literally or under the doctrine of equivalents.

63. The claims of the Patents-in-Suit are invalid under the provisions of 35 U.S.C. §§ 101 *et seq*.

64. Impax is entitled to a declaratory judgment that its venlafaxine hydrochloride extended release product does not infringe the '171 Patent.

65. Impax is entitled to a declaratory judgment that its venlafaxine hydrochloride extended release product does not infringe the '120 Patent.

66. Impax is entitled to a declaratory judgment that its venlafaxine hydrochloride extended release product does not infringe the '958 Patent.

67. Impax is entitled to a declaratory judgment that the '171 Patent is invalid and unenforceable.

68. Impax is entitled to a declaratory judgment that the '120 Patent is invalid and unenforceable.

69. Impax is entitled to a declaratory judgment that the '958 Patent is invalid and unenforceable.

PRAYER FOR RELIEF

WHEREFORE, Impax respectfully requests that this Court enter a Judgment and Order:

A. Dismissing the Complaint, and each count thereof, with prejudice and denying Wyeth any relief whatsoever;

B. Declaring the '171, '120, and '958 Patents-in-Suit to be invalid, unenforceable, and not infringed by Impax directly, by inducement of infringement, or otherwise;

C. Declaring that Impax has not willfully infringed any of the Patents-in-Suit;

D. Issuing an injunction restraining Wyeth from enforcing or attempting to enforce the Patents-in-Suit against Impax, any of Impax's suppliers, or any of Impax's customers or potential customers;

E. Declaring this case to be an exceptional case pursuant to 35 U.S.C. § 285 or otherwise, and that Impax shall be awarded its costs, together with reasonable attorneys' fees and all of its expenses for defending this suit;

F. Awarding Impax pre-judgment and post-judgment interest as allowed by law;

G. Awarding Impax any such other and further relief as the Court may deem just and proper.

Dated: April 25, 2006

Mary B. Matterer (I.D. No. 2696)
Morris James Hitchens & Williams LLP
222 Delaware Avenue, 10th Floor
Wilmington, DE 19801
(302) 888-6800
mmatterer@morrisjames.com

M. Patricia Thayer (State Bar No. 90818)
John M. Benassi (State Bar No. 74137)
Jessica R. Wolff (State Bar No. 162295)
Heller Ehrman LLP
4350 La Jolla Village Drive, 7th Floor
San Diego, California 92101
Telephone: (858) 450-8400
Facsimile: (858) 450-8499

Attorneys for IMPAX LABORATORIES, INC.

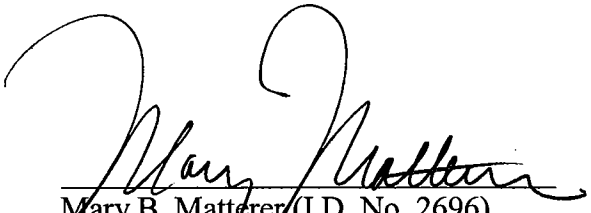
CERTIFICATE OF SERVICE

I hereby certify that on the 25th day of April, 2006, I electronically filed the foregoing document, **ANSWER AND COUNTERCLAIMS OF DEFENDANT IMPAX LABORATORIES, INC., AND DEMAND FOR JURY TRIAL**, with the Clerk of the Court using CM/ECF which will send notification of such filing to the following:

Jack B. Blumenfeld
Melissa S. Myers
Morris Nichols Arsht & Tunnell
1201 N. Market Street
Wilmington, DE 19801

Additionally, I hereby certify that on the 25th day of April, 2006, the foregoing document was served via email on the following non-registered participants:

Basil J. Lewris
Linda A. Wadler
Finnegan Henderson Farabow
Garrett & Dunner
901 New York Avenue, NW
Washington, DE 20001
Bill.Lewris@finnegan.com
Linda.Wadler@finnegan.com



Mary B. Matterer (I.D. No. 2696)
Morris James Hitchens & Williams LLP
222 Delaware Avenue, 10th Floor
Wilmington, DE 19801
(302) 888-6800
mmatterer@morrisjames.com

Attorneys for IMPAX LABORATORIES, INC.

EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WYETH, **Plaintiff,** **v.** **TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,** **Defendants.**	03-CV-1293 (WJM) **MARKMAN ORDER**

This matter comes before the Court on motions to construe certain disputed claim terms in the patents-in-suit. After having reviewed the parties' submissions, and having considered the parties' arguments made at the *Markman* hearing, and for good cause shown,

IT IS on this 6th day of September 2005, hereby

ORDERED that the disputed claim terms shall have the following meanings:

1. "extended release formulation" means "a formulation comprising venlafaxine hydrochloride, microcrystalline cellulose and, optionally, HPMC coated with a mixture of ethyl cellulose and HPMC in an amount needed to provide a specific unit dosage administered once-a-day to provide a therapeutic blood plasma level of venlafaxine over the entire 24-hour period of administration;"

2. "spheroids" means "one or more particles that are generally shaped like a sphere, although they do not have to be perfectly round;"

3. "with diminished incidence(s) of nausea and emesis" means "a decrease in the number of patients suffering from nausea and vomiting compared to patients receiving the same total daily dose of an immediate release formulation that is administered at least twice a day;"

4. "encapsulated" means "a formulation that is filled into a pharmaceutically acceptable capsule."

s/ William J. Martini
William J. Martini, U.S.D.J.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WYETH, **Plaintiff,** **v.** **TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,** **Defendants.**	03-CV-1293 (WJM) **MARKMAN OPINION**

This matter comes before the Court on the parties' submissions seeking construction of four disputed claim terms found in the patents-in-suit. Having taken into consideration the parties' submissions and their arguments made during the *Markman* hearing, the Court construes the disputed claim terms as follows.

BACKGROUND

This is an Abbreviated New Drug Application ("ANDA") patent infringement action. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. ("Teva") filed an ANDA seeking to market a generic version of Wyeth's Effexor® XR. Wyeth filed suit, alleging Teva's generic extended release venlafaxine formulation infringes three of its patents: U.S. Patent Nos. 6,274,171 B1 (the "'171 patent"), 6,419,958 B2 (the "'958 patent"), and 6,403,120 B1 (the "'120 patent"). The three patents are related and share an essentially identical specification.

Wyeth charges Teva with infringement of claims 20-25 of the '171 patent, claims 1-6 of the '958 patent, and claims 1, 2, 13 and 14 of the '120 patent. These claims are all method claims and are directed towards a method of administering an extended release formulation of venlafaxine hydrochloride that provides a therapeutic blood plasma concentration of venlafaxine over twenty-four hours. The specification states that the extended release formulation provides two advantages over the immediate release formulation. First, it eliminates the sharp peaks and troughs in blood plasma drug levels caused by multiple daily dosing with conventional immediate release venlafaxine hydrochloride tablets. '171 patent, col. 2, lines 24-28.[1] Thus, rather than take two to three doses a day, patients need only take the extended release formulation once a day. Second, it reduces the side effects experienced by patients who have taken the immediate release tablets. *See id.* at col. 2, lines 46-55. The extended release formulation was found to reduce the incidence of nausea and emesis (the act of vomiting). According to Wyeth, these two advantages provided improved patient compliance and tolerability, making Effexor® XR a blockbuster drug. (*See* Wyeth's Br. at 2).

Although the named inventors attempted to develop an extended release formulation in the form of a tablet, they failed, finding it "impossible" to achieve a sustained release tablet formulation. Col. 10, lines 53-57. They did, however, succeed in developing a film-coated spheroid formulation that could be administered in a capsule. The specific formulation they found worked was composed of "venlafaxine hydrochloride, microcrystalline cellulose and,

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[1]Because the patents-in-suit share an essentially identical specification, all future citations will be to the '171 patent unless otherwise noted.

optionally, hydroxypropylmethylcellulose coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose." Col. 2, line 67 - col. 3, line 2.

Prior to submitting their *Markman* briefs, the Court required the parties to submit a Joint Claim Construction Chart ("Chart") setting forth the claim terms in dispute and the parties' respective proposed constructions for each term. The parties identified four disputed claim terms: "extended release formulations," "spheroid," "with diminished incidence(s) of nausea and emesis," and "encapsulated." (*See* Chart). For claim construction purposes, the following claims are illustrative of how these terms are used. Claims 20 and 21 of the '171 patent recite:

> 20. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.
>
> 21. A method for eliminating the troughs and peaks of drug concentration in a patients [sic] blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

Claims 1 and 14 of the '120 patent recite:

> 1. A method for providing therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an extended release formulation that provides peak blood plasma levels of venlafaxine of no more than about 150 ng/ml, said formulation containing venlafaxine hydrochloride as the active ingredient.
>
> 13. The method of claim 1 wherein the extended release formulation comprises venlafaxine hydrochloride in an encapsulated spheroid.

DISCUSSION

I. Law of Claim Construction

The Federal Circuit en banc recently reaffirmed the claim construction methodology articulated by *Markman v. Westview Instruments, Inc.*[2] and its progeny and clarified the role that dictionaries play in claim construction. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). In *Phillips*, the Federal Circuit reestablished the primacy of the intrinsic evidence – the claims, specification and prosecution history – and reclassified dictionaries as part of the less significant extrinsic evidence. In doing so, the Federal Circuit emphasized the need to construe the claims in their proper context, which is the specification. *Id.* at 1321.

The objective of claim construction is to determine how a person of ordinary skill in the art would understand the claim terms. *Id.* at 1313, 1324. Generally, claim terms are given their ordinary and customary meaning. *Id.* at 1312-13 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). That meaning "is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1313. In determining the ordinary meaning of claim terms, the person of ordinary skill in the art is deemed to read the claim terms in the context of the entire patent, including the particular claims in which they appear and the specification. *Id.* at 1313.

The claims "provide substantial guidance as to the meaning of particular claim terms." *Id.* at 1314. Oftentimes, the context in which a term is used in asserted and unasserted claims

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[2] 52 F.3d 967 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996).

"can be highly instructive." *Id.* Further, differences among claims can provide useful insight into a term's meaning. *Id.*

But the claims cannot be looked at in isolation; rather, they must be considered in view of the specification. *Id.* at 1315. The specification is considered to be the "single best guide" for construing the claims. *Id.* The specification may reveal whether the patentee acted as his own lexicographer by giving a claim term a special definition. *Id.* Or, it may show that the patentee intentionally disclaimed claim scope. *Id.* In either case, the patentee's intent is dispositive. *Id.*

A court should also consider the prosecution history, if it is in evidence. *Id.* at 1317. The prosecution history "consists of the complete record of the proceedings before the [Patent and Trademark Office ("PTO")] and includes the prior art cited during the examination of the patent." *Id.* (citing *Autogiro Co. of Am. v. United States*, 181 Ct. Cl. 55, 384 F.2d 391, 399 (1967)). Although it "often lacks the clarity of the specification and thus is less useful for claim construction purposes," the prosecution history sheds light on the PTO's and inventor's understanding of the patent. *Id.*

A court may, in its discretion, consult extrinsic evidence, i.e., dictionaries, treatises, and expert and inventor testimony, when construing claim terms. *Id.* A court may consult extrinsic evidence to educate itself about the field of the invention and to aid its understanding of what one of ordinary skill in the art would understand a claim term to mean. *Id.* at 1319. But extrinsic evidence is "less significant" and "less reliable" than intrinsic evidence because it gives meaning to a claim term in the abstract, rather than in the particular context of the patent. *Id.* at 1317-18. Thus, although it may play a supporting role in claim construction, extrinsic evidence may not be used to contradict an unambiguous meaning established by the intrinsic record. *See id.* at 1324.

II. The Disputed Claim Terms

1. "extended release formulation"

Wyeth contends that "extended release formulation" should be given its ordinary meaning and construed as "[a] formulation which releases the active ingredient at a slower rate than the immediate release formulation of the active ingredient such that the dosing frequency is once-a-day rather than the plural daily dosing for the immediate release formulation." (Chart). Teva asserts that the patentees acted as their own lexicographers by identifying certain ingredients that must be present in the formulation. Teva asserts that "extended release formulation" means "[a] formulation comprising venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose in an amount needed to provide a specific unit dosage administered once-a-day to provide a therapeutic blood plasma level of venlafaxine over the entire 24-hour period of administration." (*Id.*, emphasis added). Because the Court agrees with Teva that the patentees acted as their own lexicographers, the Court will adopt Teva's proposed claim construction.

The Court begins by looking at the context in which the term "extended release formulation" is used in the claims of the patents-in-suit. Wyeth argues that the asserted claims demonstrate that the patentees did not intend to limit "extended release formulation" to any specific set of ingredients. Every asserted claim recites: "A method . . . which comprises administering orally to a patient in need thereof, an . . . extended release formulation . . ., said formulation containing venlafaxine hydrochloride as the active ingredient." (*See, e.g.*, '171 patent, claim 20, emphasis added). Wyeth argues that if in fact "extended release formulation"

encompassed particular ingredients, including venlafaxine hydrochloride, then the limitation "said formulation containing venlafaxine hydrochloride as the active ingredient" would be superfluous. (Wyeth's Br. at 11). According to Wyeth, if "extended release formulation" already included venlafaxine hydrochloride, then there is no need for the claims to specify the active ingredient. Thus, argues Wyeth, "extended release formulation" does not include any particular ingredients.

Wyeth also contends that the doctrine of claim differentiation supports its broad construction of "extended release formulation." The doctrine of claim differentiation gives rise to a presumption that a limitation added in a dependent claim is not present in the independent claim. *Phillips*, 415 F.3d at 1314-15. Comparing independent claim 1 of the '120 patent with dependent claim 3, Wyeth argues that the doctrine creates a presumption that "extended release formulation" does not include specific ingredients. (Wyeth's Br. at 13). Independent claim 1 recites: "A method . . . which comprises administering orally to a patient in need thereof, an extended release formulation . . ., said formulation containing venlafaxine hydrochloride as the active ingredient." '120 patent, claim 1 (emphasis added). Dependent claim 3 recites: "The method of claim 1 wherein the extended release formulation comprises venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride, microcrystalline cellulose and optionally, hydroxypropylmethylcellulose." '120 patent, claim 3 (emphasis added). Because claim 3 includes the additional limitation of specific ingredients, the Court agrees with Wyeth that a presumption arises that claim 1 does not include that limitation. Thus, the Court agrees with Wyeth that the plain language of the claims implies that "extended release formulation" does not include specific ingredients.

Teva does not dispute that the claims, on their face, imply a broad construction for "extended release formulation." Rather, Teva argues that the presumption the broader construction applies is overcome by the narrow definition given to "extended release formulation" by the patentees in the specification. This Court agrees.

The patentees defined "extended release formulation" several times in the specification. In the abstract, they disclosed:

> More particularly, the invention comprises an extended release formulation of venlafaxine hydrochloride comprising a therapeutically effective amount of venlafaxine hydrochloride in spheroids comprised of venlfaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose.

'171 patent, Abstract. They reiterated this same restrictive definition in the "Brief Description of the Invention:"

> The formulations of this invention comprise an extended release formulation of venlafaxine hydrochloride comprising a therapeutically effective amount of venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose.

'171 patent, col. 2, line 62 - col. 3, line 2. Only after setting forth this description of their invention, did the inventors then go on to address the preferred embodiments of their invention. *See* '171 patent, col. 3, lines 5-62. Similarly, in the "Detailed Description of the Invention," the patentees defined "extended release formulations" by their ingredients:

> The extended release formulations of this invention are comprised of [venlafaxine] hydrochloride in admixture with microcrystalline cellulose and hydroxypropylmethylcellulose. Formed as beads or

> spheroids, the drug containing formulation is coated with a mixture of ethyl cellulose and hydroxypropylmethyl cellulose [sic] to provide the desired level of coating . . . .

'171 patent, col. 4, lines 9-15 (emphasis added).

Wyeth asserts that these statements merely identify a preferred embodiment of the invention. The Court disagrees. Because the specification definitively states that the "extended release formulations" of the invention are limited to particular ingredients, the Court finds that the patentees acted as their own lexicographers and limited the meaning of "extended release formulation." *See Astrazeneca AB v. Mutual Pharm. Co.*, 384 F.3d 1333, 1339-40 (Fed. Cir. 2004) (finding that the inventors acted as their own lexicographers and limited the term "solubilizer" to surfactants by stating in the specification that "[t]he solubilizers suitable according to the invention are defined below", and later describing the suitable solubilizers as surfactants).

Moreover, the specification provides additional support for a narrow construction of "extended release formulation." Although it is improper to limit the claims based on the preferred embodiments, the Federal Circuit has stated that the "preferred embodiments can shed light on the intended scope of the claims." *Id.* at 1340. Here, the specification sets forth seven examples describing different embodiments the named inventors worked with. Each and every embodiment of an "extended release formulation" recited in these examples includes venlafaxine hydrochloride, microcrystalline cellulose and, optionally, HPMC[3] coated with ethyl cellulose and HPMC. *See, e.g.*, '171 patent, col. 5, line 33 - col. 10, line 57. The fact that all of these examples use the same core set of ingredients buttresses the conclusion that "extended release

[3]"HPMC" is the abbreviation for "hydroxypropylmethylcellulose."

formulation" should be narrowly construed. *See Astrazeneca*, 384 F.3d at 1340-41 (finding additional support for a limited construction of "solubilizer" in the fact that "all of the solubilizers listed in the specification and used in the working examples were surfactants").

Further, the specification distinguishes the "extended release formulations" of the invention from extended release hydrogel tablet formulations. Wyeth admits that under its proposed construction, an extended release hydrogel tablet having the claimed *in vivo* characteristics may fall within the asserted claims. (*See* Wyeth's Br. at 16 n.6). The specification, however, discloses that the inventors' attempts to develop extended release hydrogel tablets were "fruitless" and teaches one of ordinary skill that it is "impossible to achieve" the desired dissolution rates using hydrogel tablet technology. Col. 4, lines 60-64; col. 10, lines 53-57. These statements were made without qualification. Accordingly, the specification supports construing "extended release formulation" more narrowly than Wyeth proposes. *See Cultor Corp. v. A.E. Staley Mfg. Co.*, 224 F.3d 1328, 1331 (Fed. Cir. 2000) ("Claims are not correctly construed to cover what was expressly disclaimed.").

Wyeth responds that the specification supports its broader, ordinary meaning of the term. Wyeth asserts that Teva ignores several portions of the specification which allegedly refer only to the "extended release formulation" as including venlafaxine hydrochloride. *See, e.g.*, '171 patent, Abstract ("This invention relates to a 24 hour extended release dosage formulation and unit dosage form thereof of venlafaxine hydrochloride, an antidepressant . . . .") (emphasis added); *Id.* at col. 2, lines 14-16 ("In accordance with this invention, there is provided an extended release (ER), encapsulated formulation containing venlafaxine hydrochloride as the active drug s [sic] component . . . .") (emphasis added); *Id.* at col. 2, lines 37-44 ("Hence, in

accordance with the use aspect of this invention, there is provided a method for moderating the plural blood plasma peaks and valleys . . . which comprises administering to a patient in need of treatment with venlafaxine hydrochloride, a one-a-day, extended release formulation of venlafaxine hydrochloride.") (emphasis added). Wyeth further asserts that its broad construction is supported by those portions of the specification that compare "extended release formulations" with immediate release formulations. *See, e.g.*, '171 patent, col. 2, lines 24-37 (contrasting blood plasma profiles for both types of formulations without reference to specific ingredients). And Wyeth contends that Table 1 in the specification supports a broader construction because it allegedly teaches an ordinary artisan how to screen for other useful inactive ingredients that may work in combination with venlafaxine hydrochloride to develop an extended release venlafaxine formulation. But there is no merit to Wyeth's arguments because they ignore those portions of the specification set forth above that explicitly characterize and limit the invention to a formulation containing specific ingredients.

When the term "extended release formulation" is looked at in its proper context in the specification, this Court believes that one of ordinary skill in the art would construe the term to include specific ingredients. The unequivocal language the patentees used when describing their invention – "the invention comprises an extended release formulation of", "[t]he formulations of this invention comprise" and "[t]he extended formulations of this invention are" – rebuts the presumption established by the doctrine of claim differentiation. *See, e.g., Kraft Foods, Inc. v. Int'l Trading Co.*, 203 F.3d 1362, 1368-69 (Fed. Cir. 2000) (finding the presumption of claim differentiation overcome because the specification and prosecution history described the "protecting back panel" as one that must be relatively stiff). Although this may make certain

dependent claims coterminous and certain claim limitations superfluous, that result is inevitable and inescapable in a case such as this where the patentees act as their own lexicographers. *See Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1480 (Fed. Cir. 1998) ("[T]he doctrine of claim differentiation can not broaden claims beyond their correct scope, determined in light of the specification and the prosecution history and any relevant extrinsic evidence."); *Sule v. Kloehn Co., Ltd.*, 149 F. Supp. 2d 115, 128 (D.N.J. 2001) ("Claim differentiation is a guide, not a rigid rule. If a claim will bear only one interpretation, similarity will have to be tolerated.") (quoting *Autogiro*, 384 F.2d at 404).

The portions of the prosecution history in evidence do not alter this conclusion. Although Wyeth contends that the prosecution history supports a broader construction because the method claims were allowed without limitation to specific ingredients, given the clear and unambiguous language in the specification, the Court believes that the prosecution adds, at most, nothing more than the claims themselves reveal. That being the case, the definition provided by the specification, which is the "single best guide to the meaning of a disputed term," shall be adopted. *Vitronics*, 90 F.3d at 1582.

Because the meaning of the term can be ascertained from the intrinsic record, the Court will not rely on extrinsic evidence that suggests a broader construction. *See Phillips*, 415 F.3d at 1324 (prohibiting the use of extrinsic evidence to contradict the unambiguous meaning provided to a claim term by the intrinsic evidence). That evidence takes the term out of its all-important context in the specification and, thus, will be given no weight.

In sum, "extended release formulation" means "a formulation comprising venlafaxine hydrochloride, microcrystalline cellulose and, optionally, HPMC coated with a mixture of ethyl

cellulose and HPMC in an amount needed to provide a specific unit dosage administered once-a-day to provide a therapeutic blood plasma level of venlafaxine over the entire 24-hour period of administration."

2. "spheroid"

Wyeth contends that "spheroid" means "[o]ne or more particles that are generally shaped like a sphere, although they do not have to be perfectly round", including "granules, beads and pellets." (Chart). Teva asserts that "spheroid" means "[o]ne or more particles that are generally shaped like a sphere and result from an extrusion and spheronization process." (*Id.*, emphasis added). Essentially, although the parties agree that "spheroid" means "one or more particles that are generally shaped like a sphere," they dispute whether the term should be limited to a particular manufacturing process. Because the intrinsic evidence does not narrow the meaning of "spheroids," which connotes shape, the Court will not limit its construction to a specific manufacturing process.

The term "spheroid" is contained in asserted claims 13 and 14 of the '120 patent. Wyeth argues that these claims are drawn broadly to include any "spheroid," regardless of the method of manufacture. Claim 13 recites: "The method of claim 1 wherein the extended release formulation comprising venlafaxine hydrochloride in a spheroid." '120 patent, claim 13 (emphasis added). Claim 14 is similarly broad: "The method of claim 1 wherein the extended release formulation comprises venlafaxine hydrochloride in an encapsulated spheroid." '120 patent, claim 14 (emphasis added). Thus, the plain language of the claims does not suggest that the term "spheroid" has anything other than its ordinary meaning. Morever, the specification

uses the ordinary meaning of "spheroid," equating "beads" with "spheroids" without any apparent limitation on the method of manufacture. *See* '171 patent, col. 4, lines 12-13 ("Formed as beads or spheroids, the drug containing formulation is coated . . . ."). This ordinary, unrestricted meaning is consistent with how "spheroid" is defined in a dictionary – "[a] body that is shaped like a sphere but is not perfectly round, esp. an ellipsoid that is generated by revolving an ellipse around one of its axes." Am. Heritage College Dict. 1310 (3d ed. 1993).

Teva does not dispute that Wyeth's construction comports with the ordinary meaning of the word "spheroid." (*See* Teva's Opp'n Br. at 23). Rather, it contends that in this case the patents do not support the broader definition because they only identify one method of manufacture – the extrusion and spheronization process. For example, in the "Background of the Invention," the patentees described the process they used for making "spheroids:"

> In this situation, the extended release capsule dosage forms may be formulated by mixing the drug with one or more binding agents to form a uniform mixture which is then moistened with water or a solvent such as ethanol to form an extrudable plastic mass from which small diameter, typically 1 mm, cylinders of drug/matrix are extruded, broken into appropriate lengths and transformed into spheroids using standard spheronization equipment. The spheroids, after drying, may then be film-coated to retard dissolution.

'171 patent, col. 1, lines 38-47 (emphasis added); *see also* col. 5, lines 1-13 (stating that the addition of microcrystalline cellulose and HPMC made manufacture of spheroids with extruders possible); col. 6, lines 6-11 (stating that different extruders allowed spheroids to be made without HPMC).

Teva overreaches. Although the patents disclose only one method of manufacturing "spheroids" – the extrusion and spheronization process – it appears to be described as a preferred

method of manufacture, not the only method of manufacture. *See* '171 patent, col. 1, lines 38-47 (stating that the extended release formulations "may be formulated by" extrusion and spheronization, not must be formulated by this method). Teva appears to be attempting to import the preferred process into the claims. But there is no clear disclaimer of the term's ordinary meaning, nor do the patentees define "spheroid" as being limited to that method of manufacture. Further, the Federal Circuit has held that merely disclosing only one method of manufacture in the specification does not, by itself, limit the term to that one method. *See Vanguard Products Corp. v. Parker Hannifan Corp.*, 234 F.3d 1370, 1371-72 (Fed. Cir. 2000) (construing the word "integral" to define the relationship between layers in a gasket, and refusing to limit the formation of those layers by co-extrusion, the only manufacturing process disclosed in the specification and extolled in the prosecution history); *AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 375 F.3d 1367, 1373 (Fed. Cir. 2004).

Teva raises one additional argument to support its narrow construction. It alleges that because the patentees neither described nor enabled the making of "spheroids" by any method other than by extrusion and spheronization, the term "spheroid" should be limited to maintain the validity of claims 13 and 14. (Teva's Br. at 28). Teva notes that the named inventors were aware of other methods of making "spheroids," but did not disclose them to the public. Absent that disclosure, Teva contends that the claims are not enabled or described. This argument is flawed. A court should not construe a claim term to preserve a claim's validity unless, "after applying all the available tools of claim construction," the claim term remains ambiguous. *Liebel-Flarsheim*, 358 F.3d at 911. Here, the term "spheroid" is not ambiguous and, therefore, the Court will not embark on a validity analysis at this time.

In conclusion, the Court finds that "spheroids" should not be limited to a particular method of manufacture. As such, the Court finds that "spheroids" means "one or more particles that are generally shaped like a sphere, although they do not have to be perfectly round."

3. "with diminished incidence(s) of nausea and emesis"

The parties agree that the meaning of the term "incidence" should include "frequency" of an occurrence or event. (Chart). They disagree, however, whether it should include "degree" or "level." (*See id.*).

The claims that contain this limitation are unilluminating. *See, e.g.*, '171 patent, claims 20, 22-23. Therefore, the Court begins by looking at the specification. Both parties refer to the same passage in the specification to support their construction:

> The use of the one-a-day venlafaxine hydrochloride formulations of this invention reduces by adaptation, the level of nausea and incidence of emesis that attend the administration of multiple daily dosing. In clincial trials of venlafaxine hydrochloride ER, the probability of developing nausea in the course of the trials was greatly reduced after the first week. Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies. Thus, in accordance with this use aspect of the invention there is provided a method for reducing the level of nausea and incidence of emesis attending the administration of venlafaxine hydrochloride which comprises dosing a patient in need of treatment with venlafaxine hydrochloride with an extended release formulation of venlafaxine hydrochloride once a day in a therapeutically effective amount.

'171 patent, col. 2, lines 45-62 (emphasis added).

Both parties agree that the reference to "level," as used in the above passage, connotes degree. They disagree, however, on what affect, if any, that has on the meaning of "incidence."

Teva contends that the passage above distinguishes between "level," i.e., degree, and "incidence," i.e., frequency. Teva further points out that the claims do not use level or degree; rather, they only refer to "incidence." Wyeth contends that the passage equates "incidence" with "level," thereby broadening the meaning of the term to include degree. Wyeth also juxtaposes the above passage with an excerpt that appears earlier in the specification:

> With the plural daily dosing regimen, the most common side effect is nausea, experienced by about forty five percent of patients under treatment with venlafaxine hydrochloride. Vomiting also occurs in about seventeen percent of the patients.

'171 patent, col. 2, lines 7-11 (emphasis added). Wyeth asserts that this passage demonstrates that when the patentees meant to refer to the number of patients experiencing a side effect, they did so by stating that they were "experienced by" or "occurs in" a certain "percent" of patients. Significantly, according to Wyeth, the patentees did not equate percent with "incidence." Thus, Wyeth asserts "incidence" is broader than frequency.

Wyeth's argument is inapt. Simply because the patentees did not use the word "incidence" in the earlier passage does not by itself redefine "incidence." Rather, that passage makes clear that the patentees were concerned with the number of patients experiencing side effects, not necessarily the severity of those side effects. Moreover, the abstract states that the invention "provides a lower incidence of nausea and vomiting than the conventional tablets." '171 patent, Abstract (emphasis added). Because the only discussion of the conventional tablets in the specification that is relevant to the term "incidence" concerns the percent of patients that experienced side effects, the abstract supports a narrow construction.

Ultimately, Teva appears to be correct that the patentees drew a distinction between "level" and "incidence." Although the specification refers to both terms, the claims only recite "incidence." If indeed "incidence" meant the same thing as "level," or was broader, it begs the question why the word "level" was used in the first place. The reason must be because the patentees meant to differentiate between the two terms. It is clear from the specification that when the patentees wanted to refer to "incidence," they did. Thus, the term "incidence" will be limited to its ordinary meaning as informed by the specification.

Lastly, it is worth noting that "[t]he fact that a patent asserts that an invention achieves several objectives does not require that each of the claims be construed as limited to structures that are capable of achieving all of the objectives." *Liebel-Flarsheim*, 358 F.3d at 908. Thus, the fact that the patents may discuss a reduced "level" and "incidence" of nausea does not require that claims using the word "incidence" encompass both benefits. In addition, the "incidence" limitation is not present in all of the asserted claims. *See, e.g.*, '171 patent, claims 21, 24-25; '958 patent, claims 2, 5-6. Therefore, to the extent that Wyeth suggests that a narrow construction of this term unjustifiably excludes one of the primary benefits of the invention, namely the reduction in degree of side effects, that is not the case for all asserted claims. The asserted claims that do not contain the "incidence" limitation are obviously broader and would read on such benefits.

Furthermore, to the extent that Wyeth relies on extrinsic evidence to support its broad construction, the Court does not find that evidence particularly helpful. The specification draws a clear distinction between "incidence" and "level." General dictionary definitions that allegedly support a broader construction ignore the context within which the patents use the term. *See,*

e.g., Concise Oxford Dict. of Current English 614 (5th ed. 1964) (defining "incidence" as "range, scope, extent, of influence"). The Federal Circuit in *Phillips* warned of relying on such definitions: "[H]eavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is the specification." *Phillips*, 415 F.3d at 1321. In any event, other dictionaries define the term as limited to frequency. *See* Webster's Third New Int'l Dict. (Unabridged) 1142 (2002) (defining "incidence" as "rate, range, or amount of occurrence or influence . . . *sometimes*: the rate of occurrence of new cases of a particular disease in a population being studied") (emphasis in original); Taber's Cyclopedic Med. Dict. 1077 (19th ed. 2001) (defining "incidence" as "the frequency of new cases of a disease or condition in a specific population or group"). These dictionaries provide a common meaning that is more fitting given the distinction the specification draws between "incidence" and "level."

Wyeth's experts' opinions, which remove the term "incidence" from its proper context, are also given no weight. *See Phillips*, 415 at 1318 (stating that a court "should discount any expert testimony 'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent'") (quoting *Key Pharms. v. Hercon Labs. Corp.*, 161 F.3d 709, 716 (Fed. Cir. 1998)). Further, these experts' opinions are countered by Teva's experts, who opine that the common meaning of "incidence" is consistent with only frequency. *See* Schoenfeld Expert Report ¶ 9; Morrow Expert Report ¶ 11.

Accordingly, the Court finds that "with diminished incidence(s) of nausea and emesis" means "a decrease in the number of patients suffering from nausea and vomiting compared to

patients receiving the same total daily dose of an immediate release formulation that is administered at least twice a day."

4. "encapsulated"

Wyeth asserts that "encapsulated" means "[a] formulation that is present in a capsule, i.e., one that is filled into a pharmaceutically acceptable capsule." (Chart). Teva essentially proposes two different constructions depending on how the Court construes the term "extended release formulation." If the Court construes "extended release formulation" broadly to not include any particular ingredients, Teva contends that "encapsulated" means "[a] formulation that is present in a capsule." (*Id.*). On the other hand, if the Court construes "extended release formulation" to include particular ingredients, Teva agrees with Wyeth's narrower construction. (*See, e.g.*, Teva's Br. at 29 ("If the Court adopts Teva's construction of the term 'extended release formulation,' there is no dispute concerning the term "encapsulated.")).

Although the Court disagrees with Teva's argument that the construction of the term "encapsulated" is contingent on the construction of "extended release formulation," there appears to be no need for this Court to perform an exhaustive analysis of how this term should be construed because the Court has adopted the narrower construction of "extended release formulation." That being the case, the parties do not dispute the meaning of the term "encapsulated." Accordingly, the Court finds that "encapsulated" means "a formulation that is filled into a pharmaceutically acceptable capsule."

CONCLUSION

For the aforementioned reasons, the Court construes the disputed claim terms as follows:

1. "extended release formulation" means "a formulation comprising venlafaxine hydrochloride, microcrystalline cellulose and, optionally, HPMC coated with a mixture of ethyl cellulose and HPMC in an amount needed to provide a specific unit dosage administered once-a-day to provide a therapeutic blood plasma level of venlafaxine over the entire 24-hour period of administration;"

2. "spheroids" means "one or more particles that are generally shaped like a sphere, although they do not have to be perfectly round;"

3. "with diminished incidence(s) of nausea and emesis" means "a decrease in the number of patients suffering from nausea and vomiting compared to patients receiving the same total daily dose of an immediate release formulation that is administered at least twice a day;"

4. "encapsulated" means "a formulation that is filled into a pharmaceutically acceptable capsule."

Dated: September 6, 2005

s/ William J. Martini
William J. Martini, U.S.D.J.